UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

MIKE WILEY, Plaintiff, vs. UNITED STATES OF AMERICA, DEPT. OF HEALTH AND HUMAN SERVICES Defendant.	Case No. 2:13-cv-01210-JAD-NJK Application to Proceed *In Forma Pauperis* (Dkt. #1)

Plaintiff Mike Wiley is proceeding in this action *pro se*, has requested authority pursuant to 28 U.S.C. § 1915 to proceed *in forma pauperis*, and submitted a Complaint (Dkt. #1) on July 10, 2013. This proceeding was referred to this court by Local Rule IB 1-9.

I. *In Forma Pauperis* Application

Plaintiff has submitted the affidavit required by § 1915(a) showing an inability to prepay fees and costs or give security for them. Accordingly, the request to proceed *in forma pauperis* will be granted pursuant to 28 U.S.C. § 1915(a). The court will now review Plaintiff's complaint.

II. Screening the Complaint

Upon granting a request to proceed *in forma pauperis*, a court must additionally screen the complaint. Federal courts are given the authority to dismiss a case if the action is legally "frivolous or malicious," fails to state a claim upon which relief may be granted, or seeks monetary relief from a defendant who is immune from such relief. 28 U.S.C. § 1915(e)(2). When a court dismisses a complaint under § 1915(e), the plaintiff should be given leave to amend the complaint with directions as to curing its deficiencies, unless it is clear from the face of the complaint that the deficiencies could not be cured by amendment. *See Cato v. United States*, 70 F.3d 1103, 1106 (9th Cir. 1995).

Fed.R.Civ.P. 12(b)(6) provides for dismissal of a complaint for failure to state a claim upon which relief can be granted. Review under Rule 12(b)(6) is essentially a ruling on a question of law. *See Chappel v. Laboratory Corp. Of America*, 232 F.3d 719, 723 (9th Cir. 2000). A properly pled complaint must provide a short and plain statement of the claim showing that the pleader is entitled to relief. Fed.R.Civ.P. 8(a)(2); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Although Rule 8 does not require detailed factual allegations, it demands more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The court must accept as true all well-pled factual allegations contained in the complaint, but the same requirement does not apply to legal conclusions. *Id*. at 678-79. Mere recitals of the elements of a cause of action, supported only by conclusory allegations, do not suffice. *Id.* at 678. Moreover, where the claims in the complaint have not crossed the line from plausible to conceivable, the complaint should be dismissed. *Twombly,* 550 U.S. at 570. Allegations of a *pro se* complaint are held to less stringent standards than formal pleading drafted by lawyers. *Hebbe v. Pliler*, 627 F.3d 338, 342 & n.7 (9th Cir. 2010) (finding that liberal construction of *pro se* pleadings is required after *Twombly* and *Iqbal*).

In addition, federal courts are courts of limited jurisdiction and possess only that power authorized by the Constitution and statute. *See Rasul v. Bush*, 542 U.S. 466, 489 (2004). The Court must analyze whether subject matter jurisdiction exists, as it is required to dismiss the action if at any time it determines that it lacks subject matter jurisdiction. *See* Fed.R.Civ.P. 12(h)(3).

A. Factual Background

Plaintiff alleges a Federal Torts Claim Act claim against the United States of America and the Department of Health and Human Services, which is an agency of the United States of America. Docket No. 1-1. Plaintiff alleges that, on July 13, 2012, he underwent open heart surgery to repair the damage caused by a "massive aortic aneurysm Type A and B." *See id.* at 7. During the surgery, Plaintiff received an injection of a cardioplegic solution manufactured by the New England Compounding Center ("NECC"). *Id*. For approximately 90 days after his surgery, Plaintiff suffered from symptoms such as tinnitus, loss of sleep, skin irritation, dry eyes and mouth, lack of production of sweat and semen, little to no oil secretions from the skin, and peeling skin on both hands. *Id*.

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Plaintiff alleges that, on October 20, 2012, Sunrise Hospital informed him that the cardioplegic solution used during his surgery "was in fact a contaminated product from NECC." *Id*. The letter Plaintiff received from Sunrise Hospital, however, does not state that the cardioplegic solution was a contaminated product. *See* Docket No. 1-1, Exh. E. Instead, the October 18, 2012, letter from Sunrise's CEO informs Plaintiff that he received a cardioplegic solution during his heart surgery that had been purchased from NECC, and that the pharmacy was recently linked to infections. *Id*. The letter specifically tells Plaintiff that "[t]he medication you received has not currently been confirmed as causing infections, and authorities believe your risk is very low. Nevertheless, the U.S. Food and Drug Administration has advised us that you should be notified out of an abundance of caution." *Id*. Plaintiff also attaches a print-out from what appears to be the Centers for Disease Control and Prevention ("CDC") website dated December 3, 2012. This "CDC Health Update" speaks of additional contamination identified in medical products from NECC. *See* Docket No. 1-1, Exh. C. The update lists a cardioplegia solution produced by NECC that contains bacterial and/or fungal contamination; however, Plaintiff has not alleged that the lot number identified in this health update is the lot number from which he received his cardioplegia solution. *Id*; Docket No. 1-1.

Plaintiff alleges that the Food and Drug Administration ("FDA") an Agency within the Department of Health and Human Services, investigated NECC in 2002 and 2004, and issued findings against NECC in 2006. Docket No. 1-1, at 4. Plaintiff alleges that NECC breached its duty of care for failing to shut NECC down during this investigation "until it had corrected its poor sterility management systems." *Id*., at 8. Plaintiff claims that, but for this breach of the FDA's duty of care, he would not have been injected with a contaminated cardioplegic solution. *Id*. Plaintiff has attached to his complaint a copy of a letter sent to NECC by the FDA on December 4, 2006. Docket No. 1-1, Exh. D. This letter informs the owner of NECC that investigators from the FDA conducted an investigation of NECC beginning on September 23, 2004, and ending on January 19, 2005. *Id*. The letter states that NECC is engaged in compounding copies of commercially available drug products, and that the products are misbranded as their labels do not contain adequate directions for use. *Id*., at 2. The letter also states that NECC offers to compound "Extra Strength Triple Anesthetic Cream," and that the FDA is concerned with the public health risks associated with the compounding of this type of cream, as well as a potential labeling issue. *Id*., at 3. The letter further states that the FDA is in receipt of a complaint alleging that NECC repackages an injectible drug into syringes

for sale to health professionals, and that NECC is selling this drug in a manner not approved by the FDA. The letter advises NECC to correct these deficiencies. *Id.*, at 4. Finally, the letter advises NECC to notify the FDA in writing of any steps it will take to correct the violations, and gives it an address. *Id.*, at 4-5. Nowhere in the letter does it state that the FDA found that NECC had any issues with sterility, or "poor sterility management systems." Docket No. 1-1, at 8, Exh. D.

On December 20, 2012, Plaintiff filed an administrative tort claim, pursuant to the Federal Tort Claims Act, with the FDA. Docket No. 1-1, Exh. A. On April 16, 2013, the Department of Health & Human Services denied Plaintiff's administrative tort claim, and informed him that he may file suit in federal district court within six months of the denial letter. Docket No. 1-1, Exh. B. Plaintiff has therefore appropriately exhausted his administrative remedies.

B. State Law Duty

The Federal Tort Claims Act ("FTCA") waives the federal government's sovereign immunity for tort claims arising out of the negligent conduct of government employees and agencies in circumstances where the United States, if a private person, would be liable to the claimant under the law of the place where the act or omission occurred. *Terbush v. United States*, 516 F.3d 1125, 1128-29 (9th Cir. 2008). Courts have construed the "law of the place" in § 1346(b) to refer to the law of the state where the act or omission occurred. *See, e.g., Delta Savings Bank v. United States*, 265 F.3d 1017, 1025 (9th Cir. 2001). Thus, any duty that the United States owes to plaintiff must arise from state tort law and not from federal law. *Id.*

Plaintiff here frames his allegations as claims for negligence and negligence per se. "To bring a suit under the FTCA based on negligence per se, a duty must be identified, and this duty cannot spring from federal law. The duty must arise from state statutory or decisional law, and must impose on the defendants a duty to refrain from committing the sort of wrong alleged here." *Id.* at 1026. Similarly, to bring suit under the FTCA based on negligence, the plaintiff must identify a state law duty to refrain from committing the acts alleged. *See Quechan Indian Tribe v. United States*, 535 F. Supp. 2d 1072, 1107 (S.D. Cal. 2008).

In this case, Plaintiff alleges that the United States owed him a duty of care based on the Federal Food, Drug, and Cosmetic Act of 1938, the Kefauver-Harris Amendments of 1962 thereto, and FDA regulations found on its website. *See* Docket No. 1-1, at 5. Plaintiff has failed to identify any state

statutory or decisional law giving rise to a duty to refrain from committing the sort of wrong alleged here. The failure to cite a relevant state law is fatal to FTCA claims. *See, e.g.*, *Baires v. United States*, 2011 WL 1743224, *8 (N.D. Cal. May 6, 2011).[1]

Accordingly, the Court **DISMISSES** the complaint with leave to amend. In the event Plaintiff chooses to amend his claims, the complaint must include the state law(s) upon which his FTCA claims rely.

C. Discretionary Function Exception

Although the failure to allege a state law duty is fatal to Plaintiff's claims as alleged, the Court notes that it appears the claims are also barred by the discretionary function exception. As noted above, the FTCA waives the federal government's sovereign immunity for tort claims arising out of the negligent conduct of government employees and agencies in circumstances where the United States, if a private person, would be liable to the claimant under the law of the place where the act or omission occurred. *Terbush*, 516 F.3d at 1128-29. The discretionary function exception, however, provides the government immunity from suit for "[a]ny claim ... based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." 28 U.S.C. § 2680(a).

The discretionary function exception "marks the boundary between Congress' willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals." *Berkovitz v. United States*, 486 U.S. 531, 536 (1988). "The basis for the discretionary function exception was Congress' desire to prevent judicial second-guessing of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort." *Id.* at 536-37.

In determining the applicability of the discretionary function exception, the Court must determine (1) whether the challenged actions involve an element of judgment or choice; and (2) if a specific course of action is not specified, whether the discretion left to the government is of the kind that the discretionary

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[1] Because Plaintiff fails to provide any relevant state law, the Court declines to speculate as to which state law should apply (*i.e.*, in which state the alleged omission occurred). The Court notes that Plaintiff alleges the FDA's principal place of business is in Washington, D.C., but also alleges that NECC was located in Massachusetts.

function exception was designed to shield - actions and decisions based on considerations of public policy. *Terbush*, 516 F.3d at 1129 (discussing *Berkovitz*, 486 U.S. at 536-37). The first prong of the test "looks at the 'nature of the conduct, rather than the status of the actor' and the discretionary element is not met where 'a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow.'" *Id*. (quoting *Berkovitz*, 486 U.S. at 536). If no statute or policy exists that directs "mandatory and specific action," the court must continue to the second prong of the analysis. *Myers v. United States*, 652 F.3d 1021, 1028 (9th Cir. 2011). The second prong of the test requires the court to determine whether the discretion is the kind of discretion protected by "public policy," which means to "include decisions grounded in social, economic, or political policy." *Id*. (quoting *Terbush*, 516 F.3d at 1129). The discretionary function exception applies even if the decision constitutes an abuse of the discretion granted. *Id*.

A safety standard operates to remove discretion under the first prong of the discretionary function test when such standard is "embodied in a *specific* and *mandatory* regulation or statute which creates clear duties incumbent upon the governmental actors." *Kennewick Irrigation Dist. v. United States*, 880 F.2d 1018, 1026 (9th Cir.1989) (emphasis in original). In this case, there is no allegation by Plaintiff of any statutory, regulatory or policy mandate requiring the FDA to force a drug manufacturer to close its operation as a result of the type of letter sent to NECC on December 4, 2006, inquiring into NECC's compounding activities. Therefore, the FDA appears to have had discretion to determine what steps to take during the 2006 investigation.

As such, the court must next consider whether the judgment of the FDA was "of the kind that the discretionary function exception was designed to shield." *United States v. Gaubert*, 499 U.S. 315, 322-23 (1991) (quotation and citation omitted). The exception "protects only governmental actions and decisions based on consideration of public policy." *Id*. at 323.

The FDA's decision to send NECC a letter regarding the compounding violations, rather than causing NECC to close while it complied, was a discretionary decision that involved protected policy judgments, including the balancing of public policy decisions such as the public's need for compounded drugs and the public's interest in safe and effective drugs. *See Forsyth v. Eli Lilly and Co.*, 904 F.Supp. 1153, 1160 (D.Haw. 1995); *see also Cleveland v. United States*, 546 F.Supp.2d 732, 759 (N.D. Cal. 2008).

Plaintiff's claims as alleged fall within the discretionary function exception to the FDA and, therefore, the United States has not waived immunity for the claims which Plaintiff asserts. This Court thus has no subject matter jurisdiction over the claims in Plaintiff's complaint and Plaintiff has failed to state a claim upon which relief can be granted. *See Bailey v. Eli Lilly Co.*, 607 F. Supp. 660 (M.D.Penn. 1985) (action involving FDA's approval of a drug barred by the discretionary function exception); *Gelley v. Astra Pharmaceutical Prods., Inc.*, 466 F. Supp. 182 (D.Minn. 1979) (action alleging FDA's failure to withdraw prior approval of a drug and to enforce regulations relating to information collection and labeling changes barred by the discretionary function exception); *Gray v. United States*, 445 F. Supp. 337 (S.D.Tex. 1978) (action involving FDA's approval of a drug without warning of its adverse effects barred by the discretionary function exception).

Accordingly, the Court **DISMISSES** the complaint with leave to amend.

III. Conclusion

Accordingly, **IT IS ORDERED** that:

1. Plaintiff's request to proceed *in forma pauperis* is GRANTED. Plaintiff shall not be required to pay the filing fee of four hundred dollars ($400.00).
2. Plaintiff is permitted to maintain this action to conclusion without the necessity of prepayment of any additional fees or costs or the giving of a security therefor. This Order granting leave to proceed *in forma pauperis* shall not extend to the issuance of subpoenas at government expense.
3. The Clerk of the Court shall file the Complaint.
4. The Complaint is **DISMISSED** for failure to state a claim upon which relief can be granted and for lack of subject matter jurisdiction, with leave to amend. Plaintiff will have until **October 23, 2013** to file his Amended Complaint, if he believes he can correct the noted deficiencies. If Plaintiff chooses to amend the complaint, Plaintiff is informed that the Court cannot refer to a prior pleading (i.e., his original Complaint) in order to make the Amended Complaint complete. This is because, as a general rule, an Amended Complaint supersedes the original Complaint. *See Loux v. Rhay*, 375 F.2d 55, 57 (9th Cir. 1967). Local Rule 15-1 requires that an Amended Complaint be complete in

itself without reference to any prior pleading. Once a plaintiff files an Amended Complaint, the original Complaint no longer serves any function in the case. Therefore, in an Amended Complaint, as in an original Complaint, each claim and the involvement of each defendant must be sufficiently alleged. Failure to comply with this Order will result in the recommended dismissal of this case, without prejudice.

Dated: September 23, 2013

NANCY J. KOPPE
UNITED STATES MAGISTRATE JUDGE